Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19

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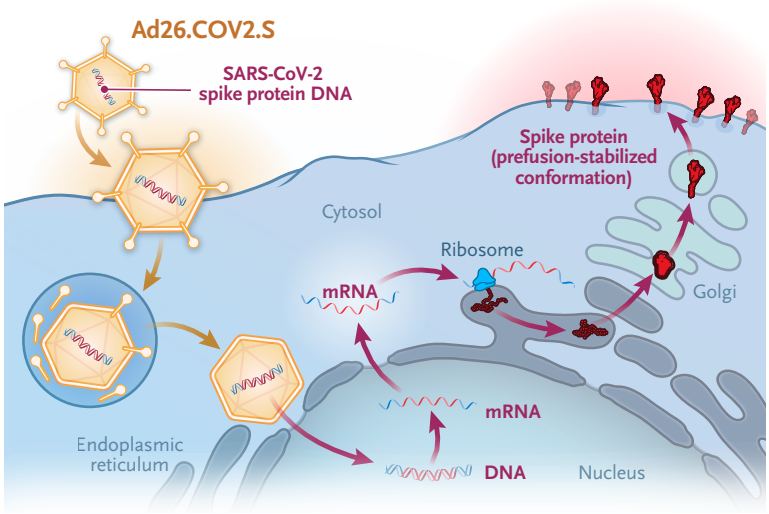


BACKGROUND

Vaccines are needed to control the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Safe adenovirus vector-based vaccines have induced durable immune responses to other diseases.

CLINICAL TRIAL

Design: A randomized, double-blind trial to evaluate the safety and efficacy of Ad26.COV2.S, a recombinant, replication-incompetent human adenovirus 26 vector encoding a full-length membrane-bound SARS-CoV-2 spike protein.

Intervention: 19,630 participants ≥18 years old were assigned to receive a single intramuscular dose of Ad26.COV2.S, and 19,691 were assigned to placebo. Participants were monitored for safety and for the occurrence of moderate to severe–critical Covid-19 with onset ≥14 days and ≥28 days after injection.

RESULTS

Efficacy: The incidence of moderate to severe–critical Covid-19 with onset ≥14 days and ≥28 days was lower among vaccine recipients. The incidences of severe–critical Covid-19 (including incidence in South Africa, despite high prevalence of the 20H/501Y.V2, or B.1.351, variant), hospitalization, and death were lower with vaccine than with placebo.

Safety: Vaccine recipients were more likely to have reactogenicity, mostly injection-site pain, as well as systemic symptoms of headache, fatigue, myalgia, or nausea. Most symptoms were mild to moderate in severity and lasted 1 to 2 days.

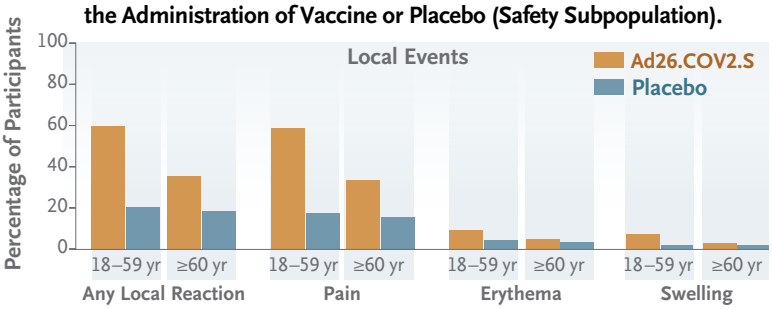
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy of Ad26.COV2.S in children.
- Long-term safety and efficacy and whether the vaccine protects against asymptomatic transmission.
- Efficacy against emerging SARS-CoV-2 variants.

Links: Full article | NEJM Quick Take

Solicited Local Adverse Events Reported within 7 days after the Administration of Vaccine or Placebo (Safety Subpopulation).



Variable	≥14 Days after Administration				
	Ad26.COV2.S (N = 19,514)		Placebo (N = 19,544)		Vaccine Efficacy (95% CI)
	no. of cases	*person-yr*	*no. of cases*	*person-yr*	%
Moderate to severe–critical Covid-19	116	3116.6	348	3096.1	66.9 (59.0–73.4)
18–59 yr	95	2106.8	260	2095.0	63.7 (53.9–71.6)
≥60 yr	21	1009.8	88	1001.2	76.3 (61.6–86.0)

Variable	≥28 Days after Administration				
Moderate to severe–critical Covid-19	66	3102.0	193	3070.7	66.1 (55.0–74.8)
18–59 yr	52	2097.6	152	2077.0	66.1 (53.3–75.8)
≥60 yr	14	1004.4	41	993.6	66.2 (36.7–83.0)

CONCLUSIONS

A single dose of Ad26.COV2.S was safe and efficacious against symptomatic Covid-19.